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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,460	12/29/2005	Etienne Pouteau	112701-697	6141

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EXAMINER	
LAU, JONATHAN S	

ART UNIT	PAPER NUMBER
1623	

NOTIFICATION DATE	DELIVERY MODE
03/19/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chicago.patents@klgates.com

Office Action Summary	Application No.	Applicant(s)	
	10/562,460	POUTEAU ET AL.	
	Examiner	Art Unit	
	Jonathan S. Lau	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 November 2008 and 24 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 24 Dec 2008 and 18 Nov 2008 has been entered.

This Office Action is responsive to Applicant's Amendment and Remarks AFTER FINAL, filed 18 Nov 2008, now entered as a matter of right, in which claims 1, 4 and 5 are amended to change the scope and breadth of the claim.

This application is the national stage entry of PCT/EP04/07092, filed 30 Jun 2004; and claims benefit of foreign priority document EP 0301486.7, filed 30 Jun 2003. This foreign priority document is in English.

Claims 1 and 3-6 are pending.

Rejections Withdrawn

Applicant's Amendment, filed 18 Nov 2008, with respect to claim 4 rejected under 35 USC 112, first paragraph as lacking enablement for the full scope of the claim has

been fully considered and is persuasive, as amended claim 4 does not recite preventing dyslipidemia.

This rejection has been **withdrawn**.

Applicant's Amendment, filed 18 Nov 2008, with respect to claim 5 rejected under 35 U.S.C. 102(b) as being anticipated by Lapré et al. (US Patent 5,972,399, issued 26 Oct 1999, of record) has been fully considered and is persuasive, as Lapré et al. does not specifically disclose the acetogenic fibre required by the claim.

This rejection has been **withdrawn**.

Applicant's Amendment, filed 18 Nov 2008, with respect to claims 5 and 6 rejected under 35 U.S.C. 102(b) as being anticipated by Eliaz (US Patent 6,462,029, issued 08 Oct 2002, of record) has been fully considered and is persuasive, as Eliaz does not specifically disclose the acetogenic fibre required by the claim.

This rejection has been **withdrawn**.

Applicant's Amendment, filed 18 Nov 2008, with respect to claims 1, 3 and 4 rejected under 35 U.S.C. 103(a) as being unpatentable over Lapré et al. (US Patent 5,972,399, issued 26 Oct 1999, of record) in view of Felter et al. (entry for wild carrot, King's American Dispensatory, 1898, of record) has been fully considered and is persuasive, as Lapré et al. in view of Felter et al. does not specifically teach the acetogenic fibre required by the claim.

This rejection has been **withdrawn**.

Applicant's Amendment, filed 18 Nov 2008, with respect to claims 1 and 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eliaz (US Patent 6,462,029, issued 08 Oct 2002, of record) in view of Felter et al. (entry for wild carrot, King's American Dispensatory, 1898, of record) has been fully considered and is persuasive, as Eliaz in view of Felter et al. does not specifically teach the acetogenic fibre required by the claim.

This rejection has been **withdrawn**.

The following are new grounds of rejection upon reconsideration of the claims as amended.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5 and 6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating and/or reducing insulin resistance in a particular type of patients having reduced insulin sensitivity, does not reasonably provide enablement for treating and/or improving insulin resistance in <u>any subject to which the instant composition is administered</u>. The specification does not enable any

person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The Applicant's attention is drawn to *In re Wands*, 8 USPQ2d 1400 (CAFC1988) at 1404 where the court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) The nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention: A method for treating and/or improving insulin resistance which comprises administering an effective amount of a composition comprising lactulose, soybean fibre, soy fibre or a mixture thereof. No limitation of the subject to which said composition is administered is required.

The state of the prior art: Hoie (US Patent Application Publication 2003/0113390, published 19 Jun 2003, cited in PTO-892) closes a composition comprising soybean fibres present in an amount of more than 6 weight % of the total weight useful for treating type 2 diabetes and/or the metabolic syndrome and the method of treating a human or animal therewith (page 22, paragraph 191 and page 31, claim 49).

Cashmere et al. (US Patent 4,921,877, issued 01 May 1990, cited in PTO-892) discloses the administration of soy polysaccharide fiber to treat insulin resistance in patients having insulin resistance (column 7, lines 20-40 and 60-65).

Hermansen et al. (US Patent Application Publication 2003/0060428, published 27 Mar 2003, cited in PTO-892) discloses a composition comprising stevioside and soy fiber for the treatment of the metabolic syndrome administered to female and male diabetic patients (page 6, paragraph 99).

The relative skill of those in the art: The relative skill of those in the art is high.

The predictability or unpredictability of the art: The sheer number of subjects to which the instant composition may be administered means that one skilled in the art cannot predict the usefulness for all possible methods of administering an effective amount of said composition. Therefore the claimed invention is unpredictable.

The Breadth of the claims: The scope of the claims is infinite. Any possible subject could potentially be used as the target of the administration of the instantly claimed method, including subjects having the optimal insulin resistance. The instantly claimed method does not require administration to a patient in need of said treatment of insulin resistance.

The amount of direction or guidance presented: The specification speaks generally about populations of people exhibiting diseases, such as diabetes. See instant PGPub at paragraphs 4-14 and 21, for example. However, guidance is not given for methods of administration of an effective amount of said composition that are not

limited to any specific subjects. In contrast, instant claim 1 requires administering to a patient having reduced insulin sensitivity.

The presence or absence of working examples: The only working examples provided are for human subjects in need of treatment at examples 1 (obese and insulin resistant subjects) and 2 (insulin resistant but have not developed full blown diabetes) spanning paragraphs 43-49.

Note that lack of working examples is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art such as methods for treating and/or improving insulin resistance which comprises administering an effective amount of a composition that are not limited to any subject of the administration, including subjects having no need for improvements to insulin resistance. See MPEP 2164.

The quantity of experimentation necessary: In order to practice the invention with the full range of all possible subjects beyond those known in the art, (such as patients in need of treatment such as patient having reduced insulin sensitivity) one skilled in the art would undertake a novel and extensive research program into the said administration of said composition. Because this research would have to be exhaustive, and because it would involve such a wide and unpredictable scope of subjects, it would constitute an undue and unpredictable experimental burden.

> *Genentech*, 108 F.3d at 1366, sates that, "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion." And "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, in view of the Wands factors, as discussed above, particularly the breadth of the claims, Applicants fail to provide information sufficient to practice the

claimed invention for all possible methods for treating and/or improving insulin resistance which comprises administering an effective amount of a composition that are not limited to any subject of the administration.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 5 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claims 1 and 5 recite “improving insulin resistance” in line 1. Claim 3 depends from claim 1 and incorporates all limitations therein. Claim 6 depends from claim 5 and incorporates all limitations therein. The term "improving insulin resistance” is a relative term that renders the claim indefinite because it is unclear whether the improvement is to increase insulin resistance, for example an improvement for subjects having insulin hypersensitivity, or to decrease insulin resistance. Claim 1 requires "administering to a patient having reduced insulin sensitivity" does not necessarily require the improvement to be to decrease insulin resistance, as said patient may have been treated with an overdose of insulin because of said patient's reduced insulin sensitivity and an improvement in that example would be to increase insulin resistance. Claim 5 recites no limitation to the subject to which the composition is administered. Dependent claim 4 remedies the relative term by specifying increasing insulin sensitivity, implicitly requiring reducing insulin resistance.

Claims 3 and 6 recite a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim), and are considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 3 recites the broad recitation “from 0.2 to 90 % by weight”, and the claim also recites narrower ranges such as “preferably from 0.5 to 50 % by weight" and “most preferred about 7 % by weight” which are narrower statements of the range/limitation. Claim 6 recites the broad recitation “from 0.1 to 1.5g per kg body weight”, and the claim also recites narrower ranges “preferably from 0.3 to 0.8g per kg body weight " and “more preferably 0.5g per kg body weight” which are narrower statements of the range/limitation.

Claims 5 and 6 recite a method for treating and/or improving insulin resistance which comprises administering an “effective amount” of a composition. The phrase “effective amount” renders the claims indefinite for failing to particularly point out and

distinctly claim the subject matter because claims 5 and 6 do not require any limitation on the subject to which said composition is administered. It is unclear what amount is effective to treat and/or improve insulin resistance when administered to a subject having the optimal insulin resistance, as the instantly claimed method encompasses administration of said composition to a subject having no need for improvement or treatment regarding insulin resistance.

Claims 5 and 6 rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the patient population to which the administration of said composition is administered to. This omitted element renders the claim indefinite because one of ordinary skill in the art would not be readily apprised of the metes and bounds of the instantly claimed method.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Amended claims 1 and 3-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Hoie (US Patent Application Publication 2003/0113390, published 19 Jun 2003, cited in PTO-892).

Hoie discloses a composition comprising soybean fibres present in an amount of more than 6 weight % of the total weight useful for treating various diseases (abstract), meeting limitations of instant claim 3. Hoie discloses said composition useful for treating type 2 diabetes and/or the metabolic syndrome (page 1, paragraph 2), which is characterized by insulin resistance and reduced insulin sensitivity (page 4, paragraph 31), meeting limitations of instant claim 1. Hoie discloses said composition used for increasing insulin sensitivity (page 22, paragraph 191 and page 31, claim 49), meeting limitations of instant claims 1, 4 and 5. Hoie discloses a preferred dosage of soybean fibers is about 50 g (page 20, paragraph 178), meeting limitations of instant claim 6. An average human male weighs about 100 kg, therefore a dosage of about 50 g is 0.5g per kg body weight.

Amended claims 1, 3, 5 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Cashmere et al. (US Patent 4,921,877, issued 01 May 1990, cited in PTO-892).

Cashmere et al. discloses the administration of soy polysaccharide fiber to treat insulin resistance (column 7, lines 20-40 and 60-65) by treating insulin response, meeting limitations of instant claim 5. Cashmere et al. discloses the patients having insulin resistance (column 8, lines 55-60), or reduced insulin sensitivity, meeting limitations of instant claim 1. Cashmere et al. discloses the administration of a composition of 500 kcal Diet A, or 500 g Diet A, with 10 g soy polysaccharide (column 7, lines 30-35), or a composition that is about 2 % by weight soy fiber, meeting limitations

of instant claim 3. Cashmere et al. discloses a 1000 kcal diet formula contains about 1000 g ingredients (Table 1 spanning columns 3 and 4) used in the approximation equating 500 kcal and 500 g stated above. Cashmere et al. discloses the administration of 10 g soy polysaccharide fiber to a man or a woman (column 7, lines 20-25), meeting limitations of instant claim 6. An average man is about 100 kg and an average woman is about 75 kg, therefore the soy polysaccharide fiber is administered in an amount of about 0.1 or 0.13 g per kg body weight.

Amended claims 1 and 3-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Hermansen et al. (US Patent Application Publication 2003/0060428, published 27 Mar 2003, cited in PTO-892).

Hermansen et al. discloses a composition comprising stevioside and soy fiber for the treatment of the metabolic syndrome (abstract). Hermansen et al. discloses patients have the metabolic syndrome if they exhibit insulin resistance and reduced insulin sensitivity (page 1, paragraphs 6 and 8). Hermansen et al. discloses the administration of 20 g soy cotyledon fibers to female and male diabetic patients (page 6, paragraph 99), meeting the limitations of instant claims 1, 5 and 6. An average man is about 100 kg and an average woman is about 75 kg, therefore the soy cotyledon fiber is administered in an amount of about 0.2 or 0.26 g per kg body weight. Hermansen et al. discloses administration of the composition comprising a standard diet and stevioside and soy fiber to increase insulin sensitivity (page 7, paragraph 112), meeting limitations of instant claim 4. Hermansen et al. discloses the composition comprising 50 g soy

protein and 20 g soy cotyledon fibers (page 6, paragraph 99), leading one of skill in the art to instantly envision a composition that is about 28 % by weight soy fiber, meeting the limitations of instant claim 3.

Conclusion

No claim is found to be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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